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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LANDAU, SHARMILA GOLLAMUDI	
ART UNIT	**PAPER NUMBER**
1616	

MAIL DATE	DELIVERY MODE
06/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/019,822	MANETTA ET AL.	
	Examiner	Art Unit	
	Sharmila Gollamudi Landau	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38 and 46-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38 and 46-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt Amendments/Remarks filed 3/21/07 is acknowledged. Claims **38 and 46-60** are pending in this application. Claims 1-37 and 39-45 stand cancelled.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendments of 3/21/07.

Claim Rejections - 35 USC § 112

The rejection of claims 51-52 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of applicant's arguments pointing to support on page 36, lines 8-10 of instant disclosure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 38, 47, 49, 52, 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/02133 to Lefevre et al in view of in view of WO 97/27841 to Edens et al in view of Hudson et al (5,881,869) in further view of Deckner et al (5,707,635).

Lefevre teaches a topical application of a combination of benzoyl peroxide and a second active ingredient in a multi-compartment dispensing system. The dispensing system contains a first composition of benzoyl peroxide and a second active ingredient selected from an antifungal agent or an antimicrobial agent. See abstract. The first and second compositions generate a final composition that is mixed upon delivery. See page 2, lines 20-30. The preferred second active agent is erythromycin, natamycin, clindamycin, or linocomycin. See page 3, lines 19-25. The ratio of the two active agents may be adjusted between the range of 1:1 to 1:50 and preferably 1:2 to 1:20. See page 4, lines 34-38. The concentration of the benzoyl peroxide is between 2-15% and the amount of erythromycin is up to 30%. See page 5. The final concentration of benzoyl peroxide in the mixed composition is 5% and 3% erythromycin.

The reference teaches the use of a viscosity agent to yield the desired viscosity and both compositions have a substantially similar viscosity. See page 4, lines 10-16. Viscosity agents for gelling are Carbopol 940 and hydroxypropylmethylcellulose. Additional viscosity agents are Carbopol Ultrez, xanthan, and carrageenans. The amount of the viscosity agent of **0.1-3%.** The solvents disclosed are ethanol, polyethylene glycol, propylene glycol, and glycerol. See page 4. Sodium hydroxide is taught to render the desired pH.

In a preferred embodiment, the first composition contains **5% benzoyl peroxide** suspended in an aqueous suspension adjusted with sodium hydroxide to a pH of 8 and **Carbopol** 940 (viscosifying agent- reads on claim 42). The second composition contains 30%

erythromycin dissolved in 96% ethanol and **Carbopol** Ultrez. The viscosity of the erythromycin composition is comparable to the viscosity of the benzoyl peroxide gel. The final composition yields an end concentration of 3% erythromycin and 5% benzoyl peroxide. See page 6, lines 9-30 and example 1.

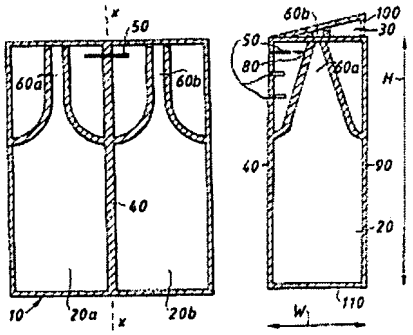
Lefevre states the actual design of the packing system is not critical as long as the dispensing system allows for separate containment as well as simultaneous dosing of the individual compositions is preferred and. Lefevre refers to the disclosure of WO 97/27841 tot each suitable dispensing system. See page, lines 10-18.

Although Lefevre teaches the dispensers taught in WO 97/27841 are suitable, Lefevre does not specify the use of two pouches in a parallel relationship that share a common side that is capable of being folded along the common side. Secondly, Lefevre does not teach the instantly claimed viscosity.

Eden teaches several dispensing systems to simultaneously dispense active agents that need to be stored separately until use wherein they are mixed together for application to the skin. Eden teaches a "simple" dispensing system wherein a pair of plastic pouches are in a parallel relationship wherein the outlets for the pouches are close together and discharge the contents upon the tearing of the opening at the end of the pouch as disclosed in DE 3630849. See page 9, lines 27-32. The bag of DE specifically is made of flexible material wherein the two pouches are side by side, sharing a common side. Example 12 teaches a dispenser with two separate pouches that dispense two separate compounds in equal volumes.

Hudson states "in industry and medicine that multi-component systems are used, whereby pre-determined amounts of several components are mixed together either shortly before use or

whilst being used." See column 1, lines 1-5. Thus, multi-components systems are used. However, Hudson states these systems have poor user compliance with inexperienced users. See column 1, lines 25-27. Thus, Hudson states a multi-component that can be used by inexperienced users is needed. See column 1, lines 35-40. Hudson teaches a package comprising multi-component packaging system (10) comprising a plurality of sealed flexible containers (20a and 20b) containing dispensable materials, each container being joined to at least one adjacent container by foldable joining means (40) whereby adjacent containers can be folded to overly each other wherein each joining means (40) is provided with tear promoting means (50) being aligned with each other to allow the overlying compartments to be torn open simultaneously with a single tearing action characterized in that the tear promoting means is arranged to promote tearing in a line transverse with respect of the direction of the fold. See abstract, column 2, lines 10-25, and Figures.



When the package is folded to dispense, the user can tear the containers simultaneously in a simple manner, which this allows a single action to empty both containers and aids in mixing of the components. See column 2, lines 65-67 and column 6, lines 4-9 and lines 55-65. Hudson teaches expelling substantially equal volumes from the containers. See column 6, lines 64-65. The fluid material contained within includes liquids, gels, and solids. See column 2, lines 24-26.

Hudson teaches the packaging system of the invention has particular application in the medical field where it is desired to mix two or more materials only at the time or point of use. See column 4, lines 33-34.

Deckner et al teach a gel type cosmetic composition which provides improved skin feel, residue characteristics, and rub-in and absorption characteristics. See abstract. Deckner teaches various suitable pharmaceuticals and preferably anti-acne drugs including benzoyl peroxide and erythromycin. See column 4, lines 5-16. The composition has a viscosity of at least 4,000, preferably 4,000-300,000, and preferably 20,000-200,000cps. See column 6, lines 44-60. Deckner teaches the use of polyacrylamide gelling agents and additional hydrophilic gels including cellulose ethers.

Firstly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lefevre (WO '133), Eden (WO '841), and Hudson et al and utilize a dispenser that has two pouches in a parallel relationship with a foldable common side wherein the packing system exists in a unfoldable form and foldable form to dispense the compositions. A skilled artisan would have been motivated to utilize the instant pouch configuration since Edens teaches a pair of plastic pouches (multi-component packaging system) in a parallel relationship with the outlets that are close together so that the contents may be discharged simultaneously upon the tearing of the opening at the end of the pouch is a simple dispensing system and Hudson teaches an improved version of Eden's pouch system wherein both containers may be opened and dispensed simultaneously in a single action; thus providing a simple and easy dispensing system. Therefore, a skilled artisan would have been motivated to utilize the instant dispensing system to provide an easy dispensing system, where both containers

may be opened and dispensed in a single action. A skilled artisan would have reasonably expected success and similar results since Lefevre states that any type of dispenser may be used, including the parallel pouch system, as long as the package provides separate containment of the benzoyl peroxide gel and erythromycin gel and yet allows simultaneous dispensing of both compositions and Hudson's system provides this critical aspect.

Secondly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further look to the teachings of Deckner et al and manipulate the viscosity of Lefevre's gel compositions. One would have been motivated to do so since Deckner teaches anti-acne gels that may have a viscosity ranging from 4,000-300,000 and 20,000-200,000 cps to increase residue, rub-in, and absorption properties. Therefore a skilled artisan would have been motivated to increase the viscosity of Lefevre's gel composition since Deckner establishes the state of the art where it is known to formulate gels particularly anti-acne (benzoyl peroxide and erythromycin) gels with viscosities ranging from 4,000-300,000 cps. Moreover, although Lefevre teaches a preferred viscosity of 100-30,000 cps, this is only a preferred range. Thus, a skilled artisan would have expected similar results since Lefevre teaches the critical aspect of the viscosity is that both compositions (the peroxide and antibiotic compositions respectively) have similar viscosities. Therefore, a skilled artisan would have been motivated to increase the viscosity of both compositions to increase its residue, rub-in, and absorption properties.

With regard to claim 52, the manipulation of the concentration of sodium hydroxide is dependent on the desired pH.

Claims 46, 48, 53-54, 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/02133 to Lefevre et al in view of in view of WO 97/27841 to

Edens et al in view of Hudson et al (5,881,869) in view of Deckner et al (5,707,635) in further view of Smith et al (5,562,642).

The disclosures of Lefevre, Edens, Hudson, and Deckner have been set forth above. Specifically, Lefevre teaches the use of a viscosity agent to yield the desired viscosity. Viscosity agents for gelling are **Carbopol** 940 and **hydroxypropylmethylcellulose**.

The combined references do not teach the instant gelling agent (HPC).

Smith et al teaches a system for applying a plurality of incompatible dermatological agents to the skin. See abstract. The composition may be in various forms such as powders, gels, dispersions, and solutions. See column 4, lines 1-2. Smith teaches the use of gelling agents, which thicken and gel aqueous-alcoholic mixtures to at least a cream or lotion consistency. Smith teaches the use of organic gelling agent such as microcrystalline cellulose, hydroxyalkyl cellulose ethers such as hydroxypropylmethylcellulose, hydroxypropylcelluose (HPC), hydroxymethylcellulose, and Carbopols etc. See column 14, lines 5-35. The gelling agent is used in the amount of 0.1% to about 15% and preferably about 0.5-3%. See column 15, lines 1-3. Furthermore, Smith teaches the use of HPC and the gelling agent of choice in combination with benzoyl peroxide, which yields a thicker fluid gel. See column 17, lines 40-68. Smith teaches the use of surfactants to stabilize the gel formulation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and substitute the prior art's gelling agent with the instant gelling agent, hydroxypropylcellulose. One would have been motivated to do so since Lefevre teaches the use of Carbopol (carbomer) or HPMC as the gelling agent in an amount of 0.1-3% and Smith teaches the functional equivalency, (both act to thicken or "gel" a

formulation) of the instantly claimed HPC and Lefevre's gelling agents (hydroxypropylmethylcellulose and carbomer). Therefore, it is prima facie obvious to substitute one equivalent component with another since the prior art establishes that both hydroxypropylcellulose and hydroxypropylmethylcellulose both function the same and are utilized for the same purpose, i.e. to thicken a skin formulation.

Claims 50-51, 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/02133 to Lefevre et al in view of in view of WO 97/27841 to Edens et al in view of Hudson et al (5,881,869) in view of Deckner et al (5,707,635) in view of Smith et al (5,562,642) in further view of Klein et al (4,692,329).

The disclosures of Lefevre, Edens, Hudson, Deckner, and Smith have been set forth above.

The references do not teach the use of instant surfactant, dioctyl sodium sulfosuccinate.

Klein et al discloses an erythromycin and benzoyl peroxide composition, wherein the actives may be packaged separately. Klein et al teach the use of dioctyl sodium sulfosuccinate to provide stability to the peroxide component in the formulation. Further, the sulfosuccinate allows evaporation and uniform release of the peroxide compound so as to avoid burning and erythema. See column 3,lines 14-25. Klein also teaches the use of various gelling agents such as Example 13 discloses a gel formulation containing 5.46% benzoyl peroxide, 2% erythromycin, 44.10% ethanol, 6% polyoxyethylene lauryl ether, 2.50 colloidal magnesium aluminum (gelling agent), 1% hydroxymethylcellulose, 0.02% dioctyl sodium sulfosuccinate, and water. Sodium hydroxide and use of Carbopol as the gelling agent is taught in examples 11-12.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the references above and further utilize the instant surfactant. One would have been motivated to do so since Klein teaches dioctyl sodium sulfosuccinate not only provides stability to a composition that contains both erythromycin and benzoyl peroxide but it also allows for the uniform release of the peroxide compound so as the avoid burning and erythema upon application. Therefore, one would be motivated to utilize the instant surfactant to increase stability and to avoid the side effects caused by the use of peroxides topically.

Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/02133 to Lefevre et al in view of in view of WO 97/27841 to Edens et al in view of Hudson et al (5,881,869).

Lefevre teaches a topical application of a combination of benzoyl peroxide and a second active ingredient in a multi-compartment dispensing system. The dispensing system contains a first composition of benzoyl peroxide and a second active ingredient selected from an antifungal agent or an antimicrobial agent. See abstract. The first and second compositions generate a final composition that is mixed upon delivery. See page 2, lines 20-30. The preferred second active agent is erythromycin, natamycin, clindamycin, or linocomycin. See page 3, lines 19-25. The ratio of the two active agents may be adjusted between the range of 1:1 to 1:50 and preferably 1:2 to 1:20. See page 4, lines 34-38. The concentration of the benzoyl peroxide is between 2-15% and the amount of erythromycin is up to 30%. See page 5. The final concentration of benzoyl peroxide in the mixed composition is 5% and 3% erythromycin.

The reference teaches the use of a viscosity agent to yield the desired viscosity and both compositions have a substantially similar viscosity. See page 4, lines 10-16. Viscosity agents for gelling are Carbopol 940 and hydroxypropylmethylcellulose. Additional viscosity agents are Carbopol Ultrez, xanthan, and carrageenans. The amount of the viscosity agent of **0.1-3%.** The solvents disclosed are ethanol, polyethylene glycol, propylene glycol, and glycerol. See page 4. Sodium hydroxide is taught to render the desired pH.

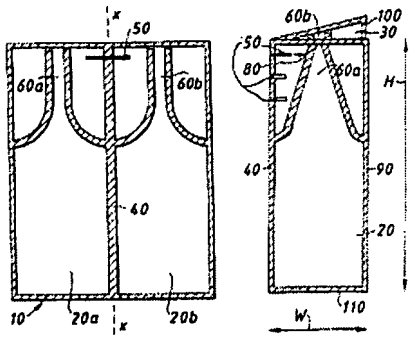
In a preferred embodiment, the first composition contains **5% benzoyl peroxide** suspended in an aqueous suspension adjusted with sodium hydroxide to a pH of 8 and **Carbopol** 940 (viscosifying agent- reads on claim 42). The second composition contains 30% **erythromycin** dissolved in 96% ethanol and **Carbopol** Ultrez. The viscosity of the erythromycin composition is comparable to the viscosity of the benzoyl peroxide gel. The final composition yields an end concentration of 3% erythromycin and 5% benzoyl peroxide. See page 6, lines 9-30 and example 1.

Lefevre states the actual design of the packing system is not critical as long as the dispensing system allows for separate containment as well as simultaneous dosing of the individual compositions is preferred and. Lefevre refers to the disclosure of WO 97/27841 tot each suitable dispensing system. See page, lines 10-18.

Although Lefevre teaches the dispensers taught in WO 97/27841 are suitable, Lefevre does not specify the use of two pouches in a parallel relationship that share a common side that is capable of being folded along the common side. Secondly, Lefevre does not teach the instantly claimed viscosity.

Eden teaches several dispensing systems to simultaneously dispense active agents that need to be stored separately until use wherein they are mixed together for application to the skin. Eden teaches a "simple" dispensing system wherein a pair of plastic pouches are in a parallel relationship wherein the outlets for the pouches are close together and discharge the contents upon the tearing of the opening at the end of the pouch as disclosed in DE 3630849. See page 9, lines 27-32. The bag of DE specifically is made of flexible material wherein the two pouches are side by side, sharing a common side. Example 12 teaches a dispenser with two separate pouches that dispense two separate compounds in equal volumes.

Hudson states "in industry and medicine that multi-component systems are used, whereby pre-determined amounts of several components are mixed together either shortly before use or whilst being used." See column 1, lines 1-5. Thus, multi-components systems are used. However, Hudson states these systems have poor user compliance with inexperienced users. See column 1, lines 25-27. Thus, Hudson states a multi-component that can be used by inexperienced users is needed. See column 1, lines 35-40. Hudson teaches a package comprising multi-component packaging system (10) comprising a plurality of sealed flexible containers (20a and 20b) containing dispensable materials, each container being joined to at least one adjacent container by foldable joining means (40) whereby adjacent containers can be folded to overly each other wherein each joining means (40) is provided with tear promoting means (50) being aligned with each other to allow the overlying compartments to be torn open simultaneously with a single tearing action characterized in that the tear promoting means is arranged to promote tearing in a line transverse with respect of the direction of the fold. See abstract, column 2, lines 10-25, and Figures.



When the package is folded to dispense, the user can tear the containers simultaneously in a simple manner, which this allows a single action to empty both containers and aids in mixing of the components. See column 2, lines 65-67 and column 6, lines 4-9 and lines 55-65. Hudson teaches expelling substantially equal volumes from the containers. See column 6, lines 64-65. The fluid material contained within includes liquids, gels, and solids. See column 2, lines 24-26. Hudson teaches the packaging system of the invention has particular application in the medical field where it is desired to mix two or more materials only at the time or point of use. See column 4, lines 33-34.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Lefevre (WO '133), Eden (WO '841), and Hudson et al and utilize a dispenser that has two pouches in a parallel relationship with a foldable common side wherein the packing system exists in a unfoldable form and foldable form to dispense the compositions. A skilled artisan would have been motivated to utilize the instant pouch configuration since Edens teaches a pair of plastic pouches (multi-component packaging system) in a parallel relationship with the outlets that are close together so that the contents may be discharged simultaneously upon the tearing of the opening at the end of the pouch is a simple dispensing system and Hudson teaches an improved version of Eden's pouch system wherein

both containers may be opened and dispensed simultaneously in a single action; thus providing a simple and easy dispensing system. Therefore, a skilled artisan would have been motivated to utilize the instant dispensing system to provide an easy dispensing system, where both containers may be opened and dispensed in a single action. A skilled artisan would have reasonably expected success and similar results since Lefevre states that any type of dispenser may be used, including the parallel pouch system, as long as the package provides separate containment of the benzoyl peroxide gel and erythromycin gel and yet allows simultaneous dispensing of both compositions and Hudson's system provides this critical aspect.

Conclusion

All the claims are rejected at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila Gollamudi Landau whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharmila Gollamudi Landau
Primary Examiner
Art Unit 1616

SGL